

**9.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(C).

**Re:** 510(k) Pre-market Notification

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**Date:** May 16, 1996

**Device Name:** LUNAR Report Generator

**Common Name:** Report Generator

**Trade Name:** Lunar Corporation Report Generator

**Classification Name:** 21 CFR 892.1170, Bone Densitometer

**Predicate Device:** K 93 4040  
The OsteoReport

**9.1 DESCRIPTION OF THE DEVICE:**

The LUNAR Report Generator is provided as a software accessory to Lunar Corporation DPX and EXPERT bone mineral densitometers. The Report Generator assists the physician in communicating densitometer results to the patient and the patient's referring physician.

The reports are generated with data received from the densitometer and physician comments. The Report Generator includes a dedicated word processing program so the physician may add comments to the data provided. The densitometer data is not modified by the Report Generator.

The report is used under the complete and absolute control of the physician. The report does not:

- interpret or advise the physician,
- diagnose osteoporosis,
- assign a level of risk for fracture based upon bone density,
- make treatment recommendations.

## 9.2 CONCLUSION

The LUNAR Report Generator is a safe device. All reports are generated under the supervision of the physician. The Report Generator does not perform any automated analysis of bone mineral densitometer data or provide any new or modified output.

  
Signed

Gary Syring  
Printed Name

Director, Regulatory Affairs  
Title

16 May '76  
Date